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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,522	11/01/2001	Mazen H. Hanna	0114.00	4387

21968 7590 07/29/2003

NEKTAR THERAPEUTICS
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EXAMINER

BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/29/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,522

Applicant(s)

HANNA ET AL.

Examiner

Rachel M. Bennett

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 1956.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 230-39, 41-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 20-39, 41 and 42 in Paper No. 7 is acknowledged.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 20-23, 25, 26-39, 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by York et al. (US 5795594).

Applicants claim a particulate coformulation of an active substance and an additive, which is a solid dispersion of one component in the other, but which has a finite gradient in the relative additive concentration, which concentration increases radially outwards from the core to the surface of the particles.

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York discloses particulate products which may be prepared by methods and apparatus using supercritical fluids. More particularly, pharmaceutical products, in particular easily handled and easily fluidized crystalline forms of salmeterol xinafoate, with controlled particle size and shape. See abstract. York discloses an apparatus for the formation of a particulate product in a controlled manner utilizing a supercritical fluid particle formation system. The apparatus comprises a particle formation vessel with means for controlling the temperature of said vessel and means for controlling the pressure of said vessel, together with a means for the co-introduction into said vessel of a supercritical fluid and a vehicle containing at least one substance in solution or suspension, into said vessel, such that dispersion and extraction of the vehicle occur substantially simultaneously by the action of the supercritical fluid. See col. 2 lines 47-58. The simultaneous co-introduction of the vehicle containing at least one substance in solution or suspension and the supercritical fluid allows a high degree of control of parameters such as temperature, pressure and flow rate, of both vehicle fluid and supercritical fluid, at the exact point when they come into contact with one another. See col. 3 lines 45-51. York also discloses the compound salmeterol xinafoate in an easily handled and easily fluidized crystalline form, with a controlled particle and shape. See col. 6, lines 40-46. Preferably, the salmeterol xinafoate is within the particle size range suitable for pharmaceutical dosage forms to be delivered by inhalation. A suitable particle size range for this use is 1 to 10 microns, preferably 1 to 5 microns. See col. 7 lines 24-30. The salmeterol xinafoate may be used to prepare a pharmaceutical composition which further comprises a pharmaceutically acceptable carrier. Preferred carriers include, for example polymers such as starch and hydroxypropylcellulose, silicon dioxide, sorbitol, mannitol and lactose, all known to be taste masking agents. In a

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preferred pharmaceutical composition the salmeterol xinafoate and carrier are co-crystallized together using the process and apparatus described by York for form multicomponent particles comprising both salmeterol xinafoate and carrier. See col. 8, lines 8-18. Examples 10 and 14 disclose the preparation of salmeterol xinafoate and polymer matrix. Claim 1-14 disclose a pharmaceutical composition comprising salmeterol xinafoate together with a pharmaceutically acceptable carrier. Therefore, these claims are anticipated.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 20-39, 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over York et al. (US 5795594).

Applicants claim a particulate coformulation of an active substance and an additive, which is a solid dispersion of one component in the other, but which has a finite gradient in the

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relative additive concentration, which concentration increases radially outwards from the core to the surface of the particles.

York, as disclosed above, teaches a particulate products which may be prepared by methods and apparatus using supercritical fluids. York does not teach the active substance: taste and/or odor masking agent ratio to be sufficiently low for there to be no detectable release of the active substance for at least 30 seconds after the coformulation comes into contact with saliva in consumer's mouth.

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of York by determining a suitable ratio of active: taste and/or odor masking agent by routine experimentation because York teaches the taste and/or odor masking are used to modify the dissolution performance of the drug. See col. 18, lines 6-14. Therefore, one of ordinary skill in the art would determine the ratio of active: taste and/or odor masking agent based on the desired release of the drug.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

rmb
July 25, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
COMMUNITY CENTER 1600